K100789

510(k) SUMMARY

APR 21 2010

Trade Name:	Steerable Guide Catheter
Common Name:	Steerable Catheter
Classification Name:	Class II, Catheter Introducer, 21 CFR 870.1280
Device Code:	DRA
Manufacturer's Name:	Evalve, Inc.
Manufacturer's Address:	4045 Campbell Avenue Menlo Park, CA 94025
Corresponding Official: Title: Address: Phone:	Karuna Velusamy Senior Regulatory Affairs Associate 4045 Campbell Avenue Menlo Park, CA 94025 (650) 330-8100
Date of Preparation:	March 17, 2010
Predicate	K083793 Evalve Steerable Guide Catheter K091596 Evalve Steerable Guide Catheter K093866 Evalve Steerable Guide Catheter
Intended Use:	The Evalve Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.
Device Description:	The Steerable Guide Catheter consists of a Steerable Guide (Guide) and a Dilator provided EO sterile and for single-use only. The Steerable Guide Catheter consists of a distal and proximal catheter shaft, a radiopaque tip ring, a handle with a steering knob, a hemostasis valve with a luer lock flush port, a Dilator with a single central lumen and an atraumatic distal tip. The central lumen of the Guide allows for aspiration of air and infusion of fluids such as saline, and serves as a conduit during introduction and or exchange of the Dilator and ancillary devices (e.g. catheters) that have a maximum diameter of .204". The atraumatic distal tip of the Steerable Guide

Catheter is radiopaque to allow visualization under fluoroscopy. The Dilator consists of a radiopaque shaft, an echogenic feature at the distal tip, a hemostasis valve with a flush port and an internal lumen designed to accept ancillary devices that have a maximum diameter of 0.035" (e.g. needles or guidewires). The Steerable Guide Catheter, Dilator and accessories are packaged in two sealed Tyvek pouches, and boxed in a shelf-cardboard carton.

Comparison to Predicate:

The subject device is substantially equivalent to the predicate devices with respect to intended use, indications for use, labeling, patient contacting materials, technological and performance characteristics, ergonomics of patient-user interface, overall dimensions, packaging, and sterilization.

Substantial Equivalence:

Bench testing demonstrated that the subject device met performance specifications and is substantially equivalent to the predicate Steerable Guide Catheter and Dilator and was based in part on the evaluation of the following performance characteristics:

1. Functional Testing
2. Luer to Hemostasis Valve Housing Torque Strength
3. Handle Interface Hypotube (Distal) to Shaft Tensile Strength
4. Handle Interface Hypotube (Proximal) and Hemostasis Valve Housing to Shaft Tensile Strength
5. Force to Curve (75°±5°)
6. Force to Curve (Hard Stop)
7. Packaging Inspection
8. Bubble Emission
9. Seal Strength
10. Biocompatibility testing: Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Acute Systemic Toxicity: Systemic Injection, Acute Systemic Toxicity: Material Mediate Pyrogen, Hemocompatibility: Hemolysis, Hemocompatibility, Coagulation: Partial Thrombolplastin Time (PTT), Hemocompatibility, Complement Activation:C3a and SC5b-9.

Conclusions:	The Evalve Steerable Guide Catheter and Dilator have the same indications for use and technological characteristics and perform as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Evalve Inc.
c/o Ms. Karuna Velusamy
Senior Regulatory Affairs Specialist
4045 Campbell Ave.
Menlo Park, CA 94025

APR 21 2010

Re: K100789
Trade/Device Name: Evalve Steerable Catheter
Common Name: Catheter, Steerable
Regulation Number: 21 CFR 870.1280
Regulatory Class: II
Product Code: DRA
Dated: March 19, 2010
Received: March 22, 2010

Dear Ms. Velusamy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K100789

Device Name: Steerable Guide Catheter

Indication for Use:

The Evalve Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vehmeyer

(Division Sign-Off)
Division of Cardiovascular Devices

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